

REMARKS

Support for the amendment to the claims to recite that the antigen polypeptide is a "synthetic" polypeptide can be found in paragraph [0127] of the corresponding US Patent Publication.

The present application relates to a technique for assaying an anti-BDV antibody using a support which is capable of detecting an anti-BDV IgM antibody and an anti-BDV IgG antibody. This allows an anti-BDV antibody to be detected even if there is only an anti-BDV IgM antibody in a sample or if there is only an anti-BDV IgG antibody in the sample, thereby improving the sensitivity of detection for BDV infection.

More specifically, if there is only an anti-BDV IgM antibody in a sample, then BDV infection is detected by detecting the anti-BDV IgM antibody; if there is only an anti-BDV IgG antibody in the sample, BDV infection is detected by detecting the anti-BDV IgG antibody; or if there is anti-BDV IgM antibody and anti-BDV IgG antibody in the sample, BDV infection is detected by detecting both the anti-BDV IgM antibody and the anti-BDV IgG antibody.

In this view, the step(c) of the claim 17 has been amended to recite (c) assaying for both anti-BDV IgM antibody and anti-BDV IgG antibody which bind to the p10 BDV synthetic antigen polypeptide and the p24 BDV synthetic antigen polypeptide immobilized on the support, so as to detect the anti-BDV IgM antibody and/or the anti-BDV IgG antibody in the sample and to detect BDV infection in the subject when the anti-BDV IgM antibody, the anti-BDV IgG antibody or both the anti-BDV IgM antibody and IgG antibody is detected.

Turning now to the outstanding Office Action.

In paragraph 4, on page 3 of the Office Action, the Examiner rejects Claim 17, 20-22 and 24-26 under 35 U.S.C. § 103 as being unpatentable over Yamaguchi et al in view of Watanabe et al, as evidenced by Planz et al, and further in view of Hatalaski et al.

The Examiner notes Applicants argument that, *inter alia*, Watanabe et al does not disclose a BDV antigen polypeptide, but rather discloses a BDV p10 protein. However, the Examiner contends that the p10 protein of Watanabe et al would be considered to be an antigen polypeptide.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Neither Yamaguchi et al nor Hatalaski et al disclose a p10 BDV synthetic antigen polypeptide. Watanabe et al may disclose a BVD p10 protein, but does not disclose "a p10 BVD synthetic antigen polypeptide".

Further, Planz et al and Carbone do not provide the deficiencies which exist therein.

Yamaguchi et al discloses detecting anti-Borna disease virus p40 and p24 antibodies by ECLIA. For the detection of these antibodies, Yamaguchi et al discloses use of beads coated with "p24 BVD synthetic peptide" and "p40 BVD synthetic peptide" and use of "marked anti-rabbit IgG polyclonal antibody" or "marked anti-horse IgG polyclonal antibody".

More specifically, Yamaguchi et al discloses a technique wherein among antibodies to be trapped in the "p24 BDV synthetic peptide" and the "p40 BDV synthetic peptide" coated on the beads, IgG antibody is detected using the "marked anti-rabbit

IgG polyclonal antibody" or the "marked anti-horse IgG polyclonal antibody".

In this view, Yamaguchi et al, does not disclose detecting for IgM antibody, nor does it disclose p10 BVD synthetic polypeptide antigen.

Therefore, Yamaguchi et al discloses neither "providing a support having immobilized thereon p10 BDV synthetic antigen polypeptide and p24 BDV synthetic antigen polypeptide" nor "assaying for both anti-BDV IgM antibody and anti-BDV IgG antibody which bind to the p10 BDV synthetic antigen polypeptide and the p24 BDV synthetic antigen polypeptide immobilized on the support, so as to detect the anti-BDV IgM antibody and/or the anti-BDV IgG antibody in the sample and to detect BDV infection in the subject when the anti-BDV IgM antibody, the anti-BDV IgG antibody or both the anti-BDV IgM antibody and IgG antibody is detected" as recited in Claim 17 of the present application.

Watanabe et al may disclose detecting anti-BVD antibody by IFA using p40 recombinant protein, p24 recombinant protein, gp18 recombinant protein, p10 recombinant protein. Anti-BVD antibody is detected by Konica immunostaining HRP-1000 using a secondary antibody. However, because the secondary antibody is not described in detail, it is not clear as to whether IgG antibody is detected or IgM antibody is detected.

Watanabe et al discloses p10 recombinant protein and p24 recombinant protein, but it does not disclose either p10 BYD synthetic polypeptide antigen or p24 BDV synthetic antigen polypeptide, as claimed.

Therefore, Watanabe at al discloses neither "providing a support having immobilized thereon p10 BDV synthetic antigen

polypeptide and p24 BDV synthetic antigen polypeptide" or "assaying for both anti-BDV IgM antibody and anti-BDV IgG antibody which bind to the p10 BDV synthetic antigen polypeptide and the p24 BDV synthetic antigen polypeptide immobilized on the support, so as to detect the anti-BDV IgM antibody and/or the anti-BDV IgG antibody in the sample and to detect BDV infection in the subject when the anti-BDV IgM antibody, the anti-BDV IgG antibody or both the anti-BDV IgM antibody and IgG antibody is detected", as recited in Claim 17.

Planz et al discloses a method for detecting BVD-specific nucleic acid and the sequence of a primer used for detection of p10 protein.

However, Planz et al does not disclose detecting for IgG and IgM antibodies. Planz et al also does not disclose either p10 BVD synthetic polypeptide antigen or p24 BDV synthetic antigen polypeptide, as claimed.

Therefore, Planz et al discloses neither "providing a support having immobilized thereon p10 BDV synthetic antigen polypeptide and p24 BDV synthetic antigen polypeptide", "reacting the resulting support with a sample from a living body" nor "assaying for both anti-BDV IgM antibody and anti-BDV IgG antibody which bind to the p10 BDV synthetic antigen polypeptide and the p24 BDV synthetic antigen polypeptide immobilized on the support, so as to detect the anti-BDV IgM antibody and/or the anti-BDV IgG antibody in the sample and to detect BDV infection in the subject when the anti-BDV IgM antibody, the anti-BDV IgG antibody or both the anti-BDV IgM antibody and IgG antibody is detected", as recited in Claim 17.

Hatalski et al discloses detecting BDV antibody by ELISA using a plate coated with recombinant p40 protein, recombinant p23 protein and recombinant gp18 protein and a secondary antibody (goat anti-mouse IgG-alkaline phosphatase, goat anti-rat IgG-alkaline phosphatase, or goat anti-rat IgG and IgM-HRPO [Sigma]).

However, Hatalski et al does not disclose either p10 BVD synthetic polypeptide antigen or p24 BDV synthetic antigen polypeptide, as claimed.

Therefore, Hatalski et al discloses neither "providing a support having immobilized thereon p10 BDV synthetic antigen polypeptide and p24 BDV synthetic antigen polypeptide" or "assaying for both anti-BDV IgM antibody and anti-BDV IgG antibody which bind to the p10 BDV synthetic antigen polypeptide and the p24 BDV synthetic antigen polypeptide immobilized on the support, so as to detect the anti-BDV IgM antibody and/or the anti-BDV IgG antibody in the sample and to detect BDV infection in the subject when the anti-BDV IgM antibody, the anti-BDV IgG antibody or both the anti-BDV IgM antibody and IgG antibody is detected", as recited in Claim 17.

Carbone discloses that BDV infection is determined by detecting IgM antibody or IgG antibody. Furthermore, Carbone discloses that natural or recombinant BDV protein is used as an antigen.

However, Carbone does not disclose either p10 BVD synthetic polypeptide antigen or p24 BDV synthetic antigen polypeptide.

Therefore, Carbone discloses neither "providing a support having immobilized thereon p10 BDV synthetic antigen polypeptide and p24 BDV synthetic antigen polypeptide" or "assaying for both

anti-BDV IgM antibody and anti-BDV IgG antibody which bind to the p10 BDV synthetic antigen polypeptide and the p24 BDV synthetic antigen polypeptide immobilized on the support, so as to detect the anti-BDV IgM antibody and/or the anti-BDV IgG antibody in the sample and to detect BDV infection in the subject when the anti-BDV IgM antibody, the anti-BDV IgG antibody or both the anti-BDV IgM antibody and IgG antibody is detected", as recited in Claim 17.

As discussed above, none of Yamaguchi et al, Watanabe et al, Planz et al, Hatalski et al or Carbone disclose p10 BDV synthetic antigen polypeptide or disclose "providing a support having Immobilized thereon p10 BDV synthetic antigen polypeptide and p24 BDV synthetic antigen polypeptide", or "assaying for both anti-BDV IgM antibody and anti-BDV IgG antibody which bind to the p10 BDV synthetic antigen polypeptide and the p24 BDV synthetic antigen polypeptide immobilized on the support, so as to detect the anti-BDV IgM antibody and/or the anti-BDV IgG antibody in the sample and to detect BDV infection in the subject when the anti-BDV IgM antibody, the anti-BDV IgG antibody or both the anti-BDV IgM antibody and IgG antibody is detected", as recited in Claim 17.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested by Yamaguchi et al, alone or in combination with Watanabe et al, Planz et al, Hatalski et al or Carbone. Thus, Applicants request withdrawal of the Examiner's rejection.

In view of the amendments to the claims and the arguments set forth above, reconsideration and allowance of this application are respectfully requested.

AMENDMENT (Q80490)

U.S. Appln. No. 10/805,220

The Examiner is invited to contact the undersigned at the below listed number on any questions which might arise.

Respectfully submitted,

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